REMARKS/ARGUMENTS

Reconsideration of the above-identified application is respectfully requested. Claims 35, 37-38, 39-51 remain in the application. Claims 53-56 and 58 have been cancelled.

Request for Interference

As will be shown hereafter, at least some of the claims in this application are allowable. Applicants have previously requested that an interference be declared between the claims of this application and United States Patent No. 6,340,369 to Ferree. It is again requested that the claims of this application be put into interference with United States Patent No. 6,340,369 to Ferree, for the reasons previously requested.

Claims Rejections under 35 U.S.C. § 112, ¶1

Claims 35 and 37-51 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner's rejection is as follows:

> Because the specification, while being enabling for using therapeutic compositions comprising "early childhood" human intervertebral disc cells and a carrier that contain required and defined cell stimulants/growth factors/carrier molecules to aid in the treatment of human disc diseases or injuries, does not reasonably provide enablement for uses of such cells from adolescents or adults wherein annulus and/or nucleus cells no longer exist, or for compositions missing required/defined components or comprising carrier derivatives thereof (i.e., in that none of the claims recite each and every required component). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. *Office Action dated 5/11/04 at pages 3-4.*

The Examiner appears to be basing his position on the fact of differences between the types of disc cells. As a result thereof, the Examiner states that the specification does not enable a person skilled in the art to make and use the invention commensurate in scope with these claims. This enablement rejection is respectfully traversed. It is noted that the Examiner has not stated that the portion of the claims involving steps (a) through (f) of pending Claim 35 is not enabled. In fact, it clearly is enabled. United States Patent No. 6,080,579, a parent patent of the present application, discloses and claims the method for propagating human intervertebral disc tissue. The claims of this application carry the process of the '579 patent one step further in that

the disc cells propagated using the method of the '579 patent are used to treat human disc diseases. The Applicants do in fact set forth each and every step of the claimed method of treating human disc disease and as clearly pointed out in the accompanying Rule 132 Declaration of Dr. Helen Gruber, one of the most outstanding researchers in this field, the straight-forwardness of the claimed method which, as noted, is indeed enabled in terms of the process for propagating tissue. As Dr. Gruber points out, the only remaining step is that the surgeon places the propagated cells into a debrided segment of a degenerated disc. As clearly pointed out in Claim 45, the particular disc cells that are propagated are taken from the person to be treated, *i.e.*, from a healthy disc tissue from a disc that does not show degenerative changes, the cells are propagated and then replaced. In such a process, the Examiner is in error in that such method is not enabled. Reconsideration of the rejection is requested.

The Examiner has continued his reasoning stating:

> In contract to Applicants' arguments on pages 8-11 of the response, the issue remains that the current claims cannot work in adolescents or adults wherein annulus and/or nucleus cells no longer exist, as previously made of record.

The Examiner's statement that the current claims cannot work in adults where in annulus cells no longer exist is simply incorrect. As pointed out in the specification and reiterated by Dr. Gruber, the type of human cells obtained from expansion of disc tissue *in vitro* which are used in the claimed therapeutic opposition are cells from the annulus. There are detailed discussions of the use of annulus cells in the patent application. Furthermore, Dr. Gruber, one skilled in the art, is of the opinion that the application provides sufficient guidance to provide the claim composition using disc cells from the annulus. Lastly, the Examiner has provided no basis for his statement that in adults, annulus cells do not exist.

The Examiner further states:

> Arguments related to what Guilack et al., Aignor et al., Frick, et al. also additionally teach in their research does not address this issue, or whether these undefined cells reasonably can 'treat human disc diseases" (especially when the specification fails to define what population of disc cells to use or how). As previously made of record, the type of matrix made by disc cells is dependent on the environment these cells are placed within and on the type of disc cells used, which the claims fail to fully define.

If one is replacing diseased cells one would obviously replace the diseased cells with the same type of disc cell. As pointed out by Dr. Gruber, the propagated cells used to replace the diseased cells in the disc are annulus cells derived from a healthy disc site. Dr. Gruber goes on to point out as stated in previous responses, the notochordal cell population disappears from the disc, and the annulus cells from the inner region populate the central portion of the disc. Therefore, it is most reasonable and effective to use the annulus cells in disc cell therapy.

Lastly, the Examiner states:

> Again, as previously made of record, disc cells are a heterogeneous population of cells with different intrinsic variations in their response to mechanical stimuli, with distinct biosynthetic capabilities, where what constitutes a successful regenerative process is unclear within the art, and in which the instant specification fails to provide guidance toward overcoming these intrinsic problems in generating a potential successful "treat[ment of] human disc diseases." In other words, this is an "enablement" rejection, where one of skill in the art does not reasonably know how to use applicants' invention, as currently claimed, and where arguing that these references do not anticipate the instant invention is not on point.

Applicants' argument about the references was to their failure to show lack of enablement. Nowhere in the Applicants' response was anticipation mentioned. In fact, as shown by the Applicants' prior response, the references do not show that the claimed invention is not enabled.

Claims Rejections under 35 U.S.C. § 112, ¶2

Claims 39-51, 54 and 58 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and claim the subject matter which Applicants regard as the invention.

1. It remains confusing how it is envisioned to "treat ... a diseased or injured intervertebral disc having nucleus and annulus regions" when normal development (or disease or injury) destroys these two regions which are only normally present in healthy early childhood tissue (*i.e.*, as it relates to Claim 39).

> Claim 39 has been amended to eliminate the distinction between nucleus regions and annulus regions. Therefore, this rejection is now moot.

2. No antecedent basis remains for the recitation of "said cultured human intervertebral disc tissue" (*i.e.*, as it relates to Claim 49 and now also Claim 47).

Claims 39, 41-42, 46-47, and 49 have been amended to provide the proper antecedent basis. This rejection is now moot.

3. No proper antecedent basis now exists for the recitation of "said intervertebral disc tissue" in claim 41, and also in claims 47 & 46 where another "said human intervertebral disc tissue", "said isolated human intervertebral disc tissue" and/or 'said cultured human intervertebral disc cells", as well as another 'said isolated disc tissue", "said intervertebral disc tissue" are recited (i.e., as it relates to claims 41-51 & 54).

Claims 39, 41-42, 46-47, and 49 have been amended to provide the proper antecedent basis. This rejection is now moot.

Claims Rejections under 35 U.S.C. § 102(a)

Claims 53-56 and 58 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Chelberg *et al.* Claims 53-56 and 58 have been cancelled. This rejection is now moot.

Summary

Enablement. There is a single rejection that the claims are non-enabling. The Aapplicants have set forth valid reasons why the claims are indeed enabling including the Rule 132 Declaration of Dr. Helen Gruber. Withdrawal of this rejection is requested in light of the compelling arguments on enablement.

Indefiniteness. The Applicants have addressed each of the rejections on indefiniteness and amended the claims to obviate each rejection. This rejection should now be moot.

Prior art rejection. Claims 53-56 and 58 rejected as being anticipated by Chelberg *et al.* have been cancelled. This rejection is now moot.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Non-Fee Amendments, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on July 29, 2004.

Janet F. Sherrill